



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,644	11/30/2000	Glenn Pierce	760100.450	3051

500 7590 08/26/2002

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 08/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/729,644

Applicant(s)

PIERCE ET AL.

Examiner

Daniel Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-104 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-71 and 98-104, drawn to a bioreactor comprising nucleic acid molecules encoding a growth stimulating agent and a bioactive agent, and a biocompatible substance capable of cellular infiltration, classified in class 514, subclass 44.
- II. Claims 72-81, drawn to a method for systemic delivery of a protein from a tissue site comprising contacting the tissue site with a bioreactor comprising nucleic acid molecules encoding a cell growth stimulating agent and a bioactive agent, and a biocompatible substance capable of cellular infiltration, classified in class 514, subclass 44.
- III. Claims 82-88, drawn to a method for systemic delivery of a protein from a tissue site comprising introducing into the tissue site a bioreactor comprising nucleic acid molecules encoding a cell growth stimulating agent and a serum soluble protein, and a biocompatible substance capable of cellular infiltration, classified in class 514, subclass 44.
- IV. Claims 89-97, drawn to a method for systemic delivery of a protein from a tissue site comprising introducing into the tissue site a bioreactor comprising a biocompatible substance, a cell growth stimulating agent and a nucleic acid molecule encoding a serum soluble protein, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1636

Inventions I and II, III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes claimed are methods for systemic delivery of a protein from a tissue site. The product, however, can be used to deliver a protein such as a cell associated bioactive agent, a bioactive extracellular matrix protein, or a serum soluble paracrine agent locally (non-systemically). In addition, inventions II-IV are methods of delivering proteins, while the product as claimed can be used to deliver any bioactive compound encoded by a nucleic acid, including bioactive RNAs.

Inventions II and III-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention I is drawn to a method of delivering any nucleic acid encoded bioactive protein while inventions III and IV are drawn to methods for delivery of serum soluble proteins that are not necessarily bioactive. The inventions are not disclosed as capable of use together and, because they encompass non-overlapping embodiments (i.e. serum soluble vs. insoluble proteins; bioactive vs. non-bioactive proteins) the inventions encompass different functions and effects.

Invention IV is also distinct from inventions II and III because, while inventions II and III are limited to cell growth-stimulating agents encoded by nucleic acids, the bioreactor of invention IV comprises cell growth stimulating agents not limited to those encoded by nucleic acids. Again the inventions are not disclosed as capable of use together and, because invention

Art Unit: 1636

IV comprises embodiments not comprised by inventions II and III, they encompass different modes of operation.

Because these inventions are distinct for the reasons given above and the search required for each group encompasses distinct subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

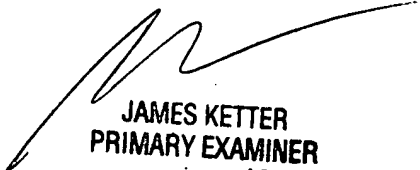
Application/Control Number: 09/729,644

Page 5

Art Unit: 1636

dms

August 2, 2002



JAMES KETTER
PRIMARY EXAMINER